Diethylene Glycol Monomethyl Ether (DGME)
Interim Registration Review Decision
Case Number 5010
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Approved by: _____

Anita Pease
Acting Director
Antimicrobials Division

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Diethylene Glycol Monomethyl Ether (DGME)
Registration Review Team

Human Health
Timothy Leighton

Environmental Fate and Effects
Laura Parsons

Risk Management
Stephen Savage
Rick Fehir

Office of General Counsel
Philip Ross

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I. Introduction

This document is the Environmental Protection Agency's (EPA or the Agency) Interim Registration Review Decision for Diethylene Glycol Monomethyl Ether (DGME) (PC Code 042204) and is being issued pursuant to 40 CFR sections 155.56 and 155.58. A registration review decision is the Agency's determination whether a pesticide meets, or does not meet, the standard for registration in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The Agency may issue, when it determines it to be appropriate, an interim registration review decision before completing a registration review. Among other things, the interim registration review decision may require new risk mitigation measures, impose interim risk mitigation measures, identify data or information required to complete the review, and include schedules for submitting the required data, conducting the new risk assessment and completing the registration review. Additional information on Diethylene Glycol Monomethyl Ether (DGME) (PC Code 042204) can be found in the Agency's public docket, which is accessible at www.regulations.gov in EPA-HQ-OPP-2010-0694.

FIFRA, as amended by the Food Quality Protection Act (FQPA) of 1996, mandated the continuous review of existing pesticides. All pesticides distributed or sold in the United States generally must be registered by the Agency based on scientific data showing that they will not cause unreasonable risks to human health or to the environment when used as directed on product labeling. The registration review program is intended to make sure that, as the ability to assess and reduce risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, the Agency periodically re-evaluates pesticides to make sure that as these changes occur, products in the marketplace can continue to be used safely. Information on this program is provided at https://www.epa.gov/pesticide-reevaluation. In 2006, the Agency implemented the registration review program pursuant to FIFRA section 3(g) and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration.

Pursuant to 40 CFR section 155.50, the Agency formally initiated registration review for Diethylene Glycol Monomethyl Ether (DGME) (PC Code 042204) in 2010. The following timeline highlights significant events that have occurred during the registration review of DGME:

- The DGME Preliminary Work Plan (PWP) was signed on December 22, 2010 and posted to the docket for a 60-day public comment period. The Agency received no comments during the public comment period which closed on February 20, 2011.

- The combined Final Work Plan (FWP) and - The Proposed Interim Decision (PID) for DGME was posted to docket EPA-HQ-OPP-2010-0694 on December 15, 2017 for a 60 day public comment. The comment period closed on February 14, 2018 and no comments were received. New data were not required and no updated or new risk assessments were determined to be needed.

1. Usage Information

The sole pesticide product containing DGME controls fungi and bacteria that can reduce fuel efficiency and foul petroleum systems. As an inert, DGME is also a de-icer that lowers the freezing point of fuel thus preventing fuel ice from forming. There is currently one registered product containing DGME, Phillips Fuel Additive 56 MB (EPA Reg. No. 224-32). DGME is formulated as a ready-to-use liquid and is sold as a 99.7% active ingredient in tanks, drums, and totes. The only potential exposure to DGME is through closed mixing and loading into fuel delivery systems. The product label prohibits open pouring and requires closed mixing and loading. Systems typically use automatic metering pumps using hoses and various connecting devices to facilitate transfer from drums, totes, holding tanks, etc.

Table 1: Registered Use for DGME

Use	Application Method	Application Rate (ppm a.i.)	Registrant	Registration Name	Registration #
Petroleum Additive and Fuel Stabilizer					
Materials Preservative: Additive in jet fuel, diesel fuel, marine fuel, and fuel oil	Closed loading	1000 – 1500	Conoco Phillips Company	Phillips Fuel Additive 56 MB	224-32

II. Scientific Assessment

A. Human Health Assessment

The Agency performed a human health risk assessment for DGME when it was first registered in 2002. The use of DGME as a materials preservative is not expected to pose a hazard to food or drinking water based on the lack of exposure. The application system is closed and there is no expected occupational exposure. The Agency does not anticipate the need for additional exposure and toxicity data for registration review and will not conduct a new human health risk assessment for DGME.

1. Risk Conclusions

The Agency believes that risks to human health from the use of DGME are expected to be minimal based on no evidence of adverse effects and lack of exposure.

2. Human Incidents

No DGME related incidents have been reported in the Agency's Incident Data System (IDS) for the period from 1992 to present, based on a search conducted on 09/13/2017. IDS contain reports of incidents from various sources, including registrants, other federal and state health and environmental agencies and individual consumers, submitted to OPP since 1992.

3. Dietary Exposure/Tolerances

There are no food uses or established tolerances in raw agricultural commodities or processed food and feed products for DGME under the Federal Food, Drug and Cosmetic Act (FFDCA) section 408. Additionally, the Federal Food and Drug Administration (FDA) has not established any clearances under FFDCA section 409. No Food Contact Notifications (FCN's) have been established for DGME.

There are no tolerances or exemptions from the requirement of a tolerance for DGME. Products containing DGME are not registered for use as an active ingredient with direct or indirect dietary exposure. Therefore, tolerances and/or exemptions are not needed for DGME.

4. Food and Drinking Water

A dietary (food and drinking water) exposure assessment is not required at this time for DGME. The only FIFRA registered use of DGME is as a materials preservative for use in petroleum fuel storage. DGME is not expected to result in direct or indirect dietary (food) exposure. The use of DGME as a materials preservative is not expected to pose a hazard to groundwater or surface waters; therefore, a drinking water assessment is not required at this time.

5. Occupational and Residential Exposures

During registration review, the registrant amended their label to restrict application of this fuel preservative to closed metered delivery systems. The label prohibits mixing or loading of DGME unless it is done through closed delivery systems and, therefore, dermal and inhalation handler exposures are expected to be minimal. In addition, the label specifies that personal protective equipment (PPE) (e.g. chemical resistant gloves, long sleeved shirt, socks, shoes, and pants) is required to be used for handling exposures such as connecting hoses or maintenance of the closed system. The end-use product contains 99.7% active ingredient (a.i.). Dermal and inhalation post-application exposures for the materials preservative used in jet, diesel, marine, and fuel oil are not expected to result in exposure contact. No additional occupational exposure data or occupational risk assessments are required at this time. No residential exposure is expected since applications are only performed in occupational settings.

6. Aggregate Exposures

An aggregate exposure risk assessment will not be conducted for this chemical because of a lack of dietary and residential exposure. DGME is only applied in fuel storage and therefore no residential exposure is expected to occur. An aggregate assessment was not necessary because there were no residential or dietary risks identified.

7. Cumulative Exposures

With respect to cumulative exposure, unlike other pesticides for which the Agency has followed a cumulative risk approach based on a common mechanism of toxicity, the Agency has not made a common mechanism of toxicity finding as to DGME and any other substances. DGME does

not appear to produce a toxic metabolite. For the purposes of this registration review, therefore, the Agency has not assumed that DGME has a common mechanism of toxicity with other substances. For information regarding the Agency's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see http://www.epa.gov/pesticides/cumulative/.

B. Environmental Assessment

The Agency has not previously conducted a risk assessment that supports a complete endangered species determination for DGME. The Agency does not anticipate any significant risks to non-endangered or endangered species. Label restrictions prevent exposure into surface water, and the environmental fate data indicate strong sorption to sediment.

Based on DGME's physical and environmental fate properties, DGME is a highly volatile substance and can easily transfer into the atmosphere; however, its half-life in air is short (4.93 hours), and it is likely to rapidly degrade. DGME is highly water soluble, and under aerobic conditions it undergoes ready biodegradation. The available ecotoxicity data categorize DGME as being practically non-toxic to birds and aquatic organisms. For more information, please refer to "Diethylene Glycol Monomethyl Ether: Product Chemistry/Environmental Chemistry and Eco-Effects Scoping Document," located in docket EPA-HQ-OPP-2010-0694.

1. Environmental Fate and Exposures

No recent ecological risk assessment has been performed for DGME. The Agency did not perform an ecological risk assessment for DGME when it was first registered in 2002 because of the limited use pattern and low chances for exposure to the environment. Based on the chemical, physical, and environmental fate properties, DGME additional environmental fate data for DGME are not required at this time.

2. Water Quality

DGME is not identified as a cause of impairment for any water bodies listed as impaired under section 303(d) of the Clean Water Act.[1] In addition, no Total Maximum Daily Loads (TMDL) have been developed for DGME.[2] More information on impaired water bodies and TMDL's can be found at the Agency's website.[3]

3. Ecological Effects Assessment

An ecological effects risk assessment will not be conducted for this chemical because of a lack of exposure to non-target organisms.

[1] http://iaspub.epa.gov/tmdl_waters10/attains_nation_cy.cause_detail_303d?p_cause_group_id=885
[2] http://iaspub.epa.gov/tmdl_waters10/attains_nation.tmdl_pollutant_detail?p_pollutant_group_id=885&p_pollutant_group_name=PESTICIDES
[3] http://www.epa.gov/owow/tmdl/

The Agency believes that ecological risks from the use of DGME, are expected to be minimal based on the environmental fate of these chemicals, which suggest negligible exposure to the environment.

4. Ecological Incidents

No DGME incidents have been reported in the Agency's Ecological Incident Information System (EIIS) for the period spanning 2000 to 2017 based on a search conducted on 09/13/2017.

C. Endangered Species Assessment

There is no reasonable expectation for the registered use of DGME to cause direct or indirect adverse effects to threatened and endangered species. No adverse modification of any designated critical habitat for such species is expected from the use of DGME. Therefore, the Agency has made a "no effect" determination under the Endangered Species Act (ESA) for all listed species and designated critical habitat for such species and has therefore concluded that consultation with the Fish and Wildlife Service and the National Marine Fisheries Service under ESA section 7(a)(2) is not required at this time.

D. Endocrine Disruptor Screening Program

As required by FIFRA and FFDCA, the Agency reviews numerous studies to assess potential adverse outcomes from exposure to chemicals. Collectively, these studies include acute, subchronic and chronic toxicity, including assessments of carcinogenicity, neurotoxicity, developmental, reproductive, and general or systemic toxicity. These studies include endpoints which may be susceptible to endocrine influence, including effects on endocrine target organ histopathology, organ weights, estrus cyclicity, sexual maturation, fertility, pregnancy rates, reproductive loss, and sex ratios in offspring. For ecological hazard assessments, the Agency evaluates acute tests and chronic studies that assess growth, developmental and reproductive effects in different taxonomic groups. As part of its most recent risk assessment for DGME, the Agency reviewed these data and selected the most sensitive endpoints for relevant risk assessment scenarios from the existing hazard database. However, as required by FFDCA Section 408(p), DGME is subject to the endocrine screening part of the Endocrine Disruptor Screening Program (EDSP).

EPA has developed the EDSP to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife, similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance, and establish a dose-response relationship between the dose and the E, A, or T effect.

Under FFDCA Section 408(p), the Agency must screen all pesticide chemicals. Between October 2009 and February 2010, EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. A second list of chemicals identified for EDSP screening was published on June 14, 2013 and includes some pesticides scheduled for registration review and chemicals found in water. Neither of these lists should be construed as a list of known or likely endocrine disruptors.

For further information on the status of the EDSP, the policies and procedures, the lists of chemicals, future lists, the test guidelines and the Tier 1 screening battery, please visit our website.

In this interim decision, the Agency is making no human health or environmental safety findings associated with the EDSP screening of DGME. Before completing this Registration Review, the Agency will make an EDSP FFDCA section 408(p) determination.

III. Interim Registration Review Decision

A. Interim Registration Review Decision

In accordance with 40 CFR Sections 155.56 and 155.58, the Agency is issuing this Interim Registration Review Decision for DGME. The Agency's Interim Decision is that no additional data are needed for the active ingredient, and no labeling changes are needed at this time. In addition, the Agency does not expect DGME to have direct or indirect adverse effects to non-listed and listed species or to adversely modify any designated critical habitat for such species and has made a "no effect" determination under the Endangered Species Act (ESA) for all listed species and designated critical habitat for such species. This interim decision does not cover the EDSP component of this registration review case, and this interim registration review decision is being issued pending its evaluation.

IV. Next Steps and Timeline

A. Interim Registration Review Decision

A Federal Register Notice will announce the availability of this Interim Registration Review Decision for DGME. The Agency's final registration review decision for DGME will be dependent upon the result of the Agency's EDSP FFDCA section 408(p) determination.

B. Implementation of Mitigation Measures

There are no risk mitigation measures or label amendments required by this Interim Decision.